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Detecting stent geometry changes after venous recanalization using duplex ultrasound

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Detecting stent geometry changes after venous recanalization using duplex ultrasound

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Abstract

Background: Patients with post-thrombotic syndrome due to chronic venous obstruction and resistant to conservative management can benefit from endovenous revascularization. The current study investigated the usefulness of duplex ultrasound in monitoring the stent changes over the time.

Method: All duplex ultrasound images of treated patients were reviewed retrospectively. The stent diameter and area during the follow-up visits have been analyzed.

Result: A total of 210 stents were placed in 137 limbs. Duplex ultrasound findings showed a decrease in area of stent in all patients (mean: 0.69 cm²). Reduction of stent area over the time was a predictor of stent patency (odds ratio: 0.910; confidence interval: 0.832–0.997).

Conclusion: Duplex ultrasound has sufficient accuracy in detection of stent changes and its patency. There is a discrepancy between diameter of the stent lumen in vitro and after deployment in all patients. Stent occlusion is related to reduction of stent lumen over the time rather than the percent of the stenosis.

Keywords

Venous recanalization, post-thrombotic syndrome, stent geometry, stent patency, ultrasound-color Doppler

Introduction

Thrombotic or non-thrombotic obstruction of the deep venous system in combination with reflux due to valve incompetence, can initiate a cascade of pathologic processes leading to venous hypertension.^{1,2} Due to the impediment of venous flow, a wide range of clinical symptoms, known as the post-thrombotic syndrome (PTS), can develop. Signs can vary from swelling to non-healing venous ulcer and symptoms can vary from feeling of heaviness in leg to disabling venous claudication.^{3,4}

Treatment of patients with PTS is primarily based on conservative management aiming to relieve the symptoms of the disease.^{5,6} Although PTS is not a life-threatening condition, it has a considerable negative effect on the quality of life and can cause significant disability.^{7,8} About 5%–10% of patients with PTS are resistant to the conventional treatment. In these cases, an individualized treatment strategy should be made to relieve the clinical symptoms of PTS.^{3,9}

These symptoms may decrease with an endovascular intervention or open surgery by reestablishing the

venous drainage pattern. Endovenous revascularization has been performed more frequent with higher success rate as before due to introduction of new imaging modalities, improved recanalization techniques and newly developed dedicated venous stents. Satisfactory clinical results (i.e. decreased pain, swelling and venous claudication, better ulcer healing, and improved Venous Disability Score) are reported after venous angioplasty with stent placement. This technique has already replaced bypass surgery and became the technique of preference for the treatment of acute or chronic iliofemoral obstructive diseases.^{10,11}

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Since stent-related problems occur mainly in the early beginning of the post intervention period, it is crucial to perform close follow-ups at regular intervals to monitor the patency of stents. When used in experienced hands, this can be performed by duplex ultrasound (DUS). Stent geometry, based on duplex findings and clinical evaluation assessment during follow-up controls are useful to determine the need for further intervention to maintain the patency of the stented tract.¹²

The aim of the current study is to investigate the efficiency of DUS in evaluating the stent geometry and early diagnosis of stent stenosis after venous angioplasty and stenting.

Material and methods

We retrospectively assessed all prospectively recorded data of patients treated by venous angioplasty and stenting from June 2012 to December 2016. All available medical records were reviewed and data on patient demographics, possible deep venous thrombosis (DVT) risk factors, clinical history, comorbidities, and identified prothrombotic conditions (panel including antithrombin, proteins C and S levels, anticardiolipin antibodies, and factor V Leiden) as well as treatment and clinical follow-up were collected.

Exclusion criteria for treatment were peripheral arterial disease, pregnancy, age under 18 years, life expectancy less than one year, and contraindication for therapeutic anticoagulation. Of all analyzed patients, 47 (38.8%) men and 74 (61.2%) women with mean age of 40.6 years (SD: 14.5) were included. A total of 121 patients (137 limbs) with acute or chronic, occlusive or non-occlusive iliofemoral disease who had venous angioplasty and stenting were included in this study.

All patients had preoperative DUS to identify the existence and also the extend of deep venous pathology. Additionally, magnetic resonance venography (MRV) or computed tomography venography (CTV) was performed to assess the extent of disease in the ilio caval and femoral segment and exclude extravascular compression causing obstruction. As a routine follow-up procedure after venous stenting in our center, DUS was performed to evaluate the iliofemoral tract up to infrarenal inferior vena cava (IVC). Two experienced sonographers performed all examinations. The DUS was performed using Philips iU22 ultrasound system (Philips Healthcare, Best, the Netherlands) and 5-10 MHz curved Transducer with a venous preset. All available gray-scale, color/power DUS images were reviewed retrospectively. To have a more precise evaluation of the stent geometry, we used DUS to measure the stent morphology as well as luminal area of the stent in different parts of the stented tract. Proximal, distal, and middle part of the stent, May-Thurner point, stent segment under the inguinal ligament and overlapping zone in cases with more than one stent were the points of interest. We also used the measured stent area and the minimum diameter at the point of maximum compression according to DUS findings before discharge and at the last follow-up just before re-intervention (Figures 1 and 2). The degree of compression was measured with ellipse and calculated as

$$\text{nominal area of stent (cm}^2\text{)} - \text{measured area of stent (cm}^2\text{)} \times 100 (\%)$$

The in vitro nominal stent diameter is the diameter provided by the stent manufacturer. The nominal stent area was calculated according to the formula: $\text{area} = 3.14 \times (\text{diameter}/2)^2$. In patients with patent

Figure 1. Longitudinal (a) and transvers (b) view of ultrasound images in a patient with May-Thurner syndrome treated using a stent with a diameter of 16 mm. External compression due to overriding right common iliac artery results a decrease in intraluminal area (measured: 1.07 cm², expected: 2.01 cm²).

Figure 2. Longitudinal ultrasound images of the stent in common iliac vein. Sufficient stenting of the May-Thurner point with proper stent coverage (a); corresponding color Doppler interrogation demonstrating patency (b).

stents without an additional intervention, the last follow-up data were used. In cases with more than one documented value of the same stent area, a mean of those was used. Patients were divided into three groups according to the onset of DVT and the extent of the venous pathology. The first group consisted of patients with chronic non-thrombotic or post-thrombotic changes without involvement of the femoral confluence (G1, $n = 48$, 39.7%). Patients with extension of the chronic post-thrombotic changes below the femoral confluence covering the ostium of deep femoral vein, in whom an endophlebectomy with insertion of arteriovenous fistula (AVF) was necessary were assorted in the second group (G2, $n = 46$, 38.0%). Patients with an acute DVT were established in the third group (G3, $n = 27$, 22.3%).

All patients with an acute DVT had ultrasound-accelerated catheter-directed lysis using the EKOS catheter (EKOS Corporation, Bothell, Washington, USA) prior to stenting. The operation techniques regarding catheter-directed lysis, percutaneous recanalization, and stenting, as well as endophlebectomy of common femoral vein with creation of AVF have been described in detail elsewhere.^{13,14}

The post procedural care consisted of thigh high compression stockings, early mobilization, and evaluation of the stent patency with DUS before discharge. All patients were also prescribed knee high compression stockings (class II) and at least 6 months of therapeutic oral anticoagulation. Clinical follow-up assessments were planned, with the performing of a DUS, at 2 weeks, 3 months, 6 months, and yearly thereafter. Subjective changes in symptoms, stent patency and the measured diameter and area of the stent lumen at the point of maximal compression were documented at each follow-up moment.

Statistical data

Continuous data are presented as median with range or mean $\pm$ SD, unless otherwise indicated. Comparisons among the groups were performed using a Student's *t* test for continuous variables with normal distribution. In categorical variables, depending on expected frequency, either Chi-square test or Fisher's exact test were performed. The Cox regression model was used for identification of variables associated with stent failure. Variables that reached statistical significance (p -value < 0.10) in univariate analysis were incorporated as covariates into the multivariate analysis. Loss of primary patency was defined as stent occlusion or an additional procedure to prevent occlusion. More than 50% in stent stenosis along with lack of clinical improvement were considered as an indication for re-intervention. Loss of assisted primary patency was defined as occlusion of the treated tract after additional interventions and loss of secondary patency defined as occlusion after initially successfully treated re-occlusion. A Kaplan–Meier survival analysis was used to calculate the patency rates. Standard error of the mean (SEM) values of $> 10\%$ were discarded as being unreliable and are not reported. A p -value of < 0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS software Version 20 (SPSS Inc, Chicago, IL). Graphs were created using GraphPad Prism version 6.00 for windows (GraphPad Software, San Diego California USA).

Result

This study included 121 patients, of whom 16 (13.2%) had bilateral treatment of the femoroiliocaval venous tract. The patient characteristics are listed in Table 1.

Table 1. Patient characteristics.

Characteristic	Total (n = 121)	G1 (n = 48)	G2 (n = 46)	G3 (n = 27)	ρ
Gender					0.086
Male, n (%)	47 (38.8)	17 (35.4)	22 (47.8)	8 (29.6)	
Female, n (%)	74 (61.2)	31 (64.6)	24 (52.2)	19 (70.4)	
Age (years), mean $\pm$ SD	40.6 $\pm$ 14.5	43.3 $\pm$ 14.9	41.3 $\pm$ 12.8	37.7 $\pm$ 15.5	0.032
BMI (kg/m ²), mean $\pm$ SD	27.1 $\pm$ 4.0	27.7 $\pm$ 4.2	27.0 $\pm$ 3.8	25.5 $\pm$ 3.8	0.229
Side of pathology					0.589
Left, n (%)	82 (67.8)	35 (72.9)	28 (60.8)	19 (70.3)	
Right, n (%)	23 (19.0)	9 (18.75)	9 (19.5)	5 (18.5)	
Both sides, n (%)	16 (13.2)	4 (8.3)	9 (19.5)	3 (11.1)	

G1: post-thrombotic involvement of ilioacaval tract + May-Thurner syndrome; G2: G1 + involvement of femoral confluence (endophlebectomy + insertion of AVF); G3: deep vein thrombosis (lysis before stenting); BMI: body mass index; AVF: arteriovenous fistula.

A total of 210 stents were placed in 137 limbs (mean: 1.5 per limb). Of all used stents, 181 (86.2%) were dedicated venous stents and 29 (13.8%) non-dedicated venous stents. In 61 limbs one stent was implanted, in 55 limbs two stents and in 14 limbs more than two stents were needed to cover the pathologic area. The mean length of stented area was 168.3 ± 71.2 mm and the mean duration of the intervention was 242 ± 166.6 min (including the patients with an endophlebectomy) (Table 2). Whenever two or more stents were deployed, the stents were overlapped by at least 1 cm to ensure adequate stent coverage of the diseased vein. The endovascular and surgical procedures were performed without perioperative or postoperative (<30 days) mortality. There were no major bleeding, cardiac, pulmonary, or renal 30-day complications.

Review of these recordings in first follow-up after endovenous revascularization showed a decrease in area of stent in all patients (mean, range in cm²; 0.69, 0.06 cm²–1.65 cm²) comparing to the nominal stent area (Figure 3). The mean percentage decrease of the stent area before the end of the primary patency or until the last follow-up was 36.52% (SD: 18.13%) (Table 2).

In the univariate analysis, the predictors of stent failure included the duration of the operation, length of stented tract and reduction of stent area over the time. In the multivariate analysis, the only significant independent predictor of stent occlusion was the reduction of stent area (odds ratio (OR), 0.910; 95% confidence interval (CI), 0.832–0.997) (Table 3).

During a median follow-up of 17 months (range: 1–65), primary patency, assisted primary patency, and secondary patency of all patients were 60.3%, 76.2%, and 87.3%, respectively (Figure 4).

Discussion

DUS is a well-established imaging method in diagnosing venous pathology as well as assessing its etiology

and extension. Moreover, it is a cost effective imaging method through posttreatment evaluations to identify stent stenosis or occlusion.^{12,15,16} It should be mentioned that the optimal assessment of in-stent changes would be to use intravascular ultrasound (IVUS) to measure wall thickness, total area of stenosis, and any vessel remodeling that may have occurred.^{11,12,26} However, cost and logistics prevents regular use of IVUS as a diagnostic tool in every follow-up controls. For the same reason, conventional venography is a suitable option mostly in patients, in whom an additional intervention is planned and not just as a screening test. In addition, conventional venography is a two-dimensional projection imaging without opacification of the nearby organs.

Alternatively, MRV could be used but is not able to reliably visualize the lumen of metallic stents due to susceptibility artifacts and radiofrequency shielding of metallic stents.^{17–19} Even nitinol stents are not artifact free on MRV images.²⁰ Subsequently, CTV remains as the gold standard with a high diagnostic accuracy to evaluate the stent geometry. It has the advantage of providing the three-dimensional images at any desired viewing angle and quality of assessment does not depend on the skill of the examiner.^{21,22} However, It is obvious that CTV does not provide hemodynamic information and benefits of CTV have to be interpreted in the light of the radiation dose and cost-effectiveness of the technique.

In the present study, we performed a comprehensive analysis of stent specification and geometry using DUS images in order to investigate its capability and efficacy in early detection of stent changes to predict the stent outcome.

Reviewing the calculated diameter and measured luminal area of the stent at the first follow-up showed that there was a discrepancy between the measured area of the stent in vivo and its nominal size in vitro (mean, range; 0.69, 0.06–1.65). According to this finding,

Table 2. Treatment aspects.

Duration of the operation (min)	Mean $\pm$ SD	242 $\pm$ 166.6
Name of stent		
Sinus venous (v*)	n (%)	131 (62.3)
Sinus XL (v)	n (%)	40 (19.1)
Sinus repo (a**)	n (%)	25 (11.9)
Sinus flex (v)	n (%)	5 (2.3)
Veniti (v)	n (%)	4 (1.9)
Andra (a)	n (%)	3 (1.5)
Advanta (a)	n (%)	1 (0.5)
Sinus obliquus (v)	n (%)	1 (0.5)
Type of stent		
Venous stent	n (%)	181 (86.2)
Arterial stent	n (%)	29 (13.8)
Number of stents per limb		
	0, n (%)	7, (5.1)
	1, n (%)	61, (44.6)
	2, n (%)	55, (40.1)
	>2, n (%)	14, (10.2)
Stented vein segments		
IVC	n (%)	29 (13.8)
LCIV	n (%)	45 (21.4)
LCIV + LEIV	n (%)	46 (21.9)
RCIV	n (%)	18 (8.6)
RCIV + REIV	n (%)	13 (6.2)
LEIV	n (%)	5 (2.4)
LEIV + LCFV	n(%)	33 (15.7)
REIV	n (%)	2 (0.9)
REIV + RCFV	n (%)	15 (7.1)
LCFV	n (%)	3 (1.5)
RCFV	n (%)	1 (0.5)
Length of stented area (mm)	mean $\pm$ SD	168.3 $\pm$ 71.2
Follow-up (month)	Median, (range)	24.50, (1–65)
Decrease in stent area (cm ²) at first follow-up (after 2 weeks)	mean $\pm$ SD, (range)	0.69 $\pm$ 0.42 (0.06–1.65)
Reduction of stent area over the time (%)	mean $\pm$ SD, (range)	36.52 $\pm$ 18.13 (3.90–83.12)

v*: venous dedicated stent; a**: arterial stent; IVC: inferior vena cava; LCIV: left common iliac vein; RCIV: right common iliac vein; LEIV: left external iliac vein; REIV: right external iliac vein; LCFV: left common femoral vein; RCFV: right common femoral vein.

Figure 3. Cross-sectional view of the stent at May-Thurner point before discharge (a) and 6 months after discharge (b) in the same patient demonstrating the reduction of stent area after 6 months (~ 0.171 cm²).

Table 3. Regression analysis of probable factors influencing the patency.

Variable	Univariate analysis			Multivariate analysis		
	OR	95% CI	p-value	OR	95% CI	p-value
Sex	0.949	0.467–1.931	0.886	1.490	0.060–36.820	0.808
Age	0.985	0.961–1.009	0.222	0.966	0.864–1.079	0.540
BMI	0.950	0.866–1.043	0.278	0.917	0.617–1.368	0.671
Duration of the operation	1.004	1.002–1.007	0.001	1.009	0.997–1.020	0.149
Side of involvement	0.722	0.204–2.551	0.765	0.303	0.013–6.942	0.455
Type of stent	1.210	0.537–2.729	0.656	0.000	0.000	—
Length of stented tract	1.006	1.001–1.010	0.015	1.015	0.995–1.035	0.132
Reduction of stent area	0.959	0.923–0.997	0.023	0.910	0.832–0.997	0.042

Chi-square: 20.93, degrees of freedom: 11, p-value: 0.034.

BMI: body mass index.

Figure 4. Cumulative primary (a), assisted primary (b), and secondary patency (c) rates after iliofemoral stenting (all standard errors of the mean <10%).

despite ballooning before and after stenting, the stents never reached its nominal size after deployment. It reveals the high compression force of adjacent organs as well as constricting tension of intraluminal fibrosis in

diseased veins and its walls. It also emphasizes the role and necessity of high radial resistive forces in venous stents to avoid collapsing the vein walls. One solution to minimize this issue is to dilate the vein always before

stent deployment to help optimal positioning of stents and prevent the recoiling phenomenon to hamper the stent expansion. Some interventionists perform predilatation up to the nominal diameter of the subsequently used stent.^{12,23} Accordingly, it may be safe to perform the predilatation with a larger balloon diameter compared to the intended stent diameter and not to be afraid of probable stent migration.

In the treatment of thrombotic obstruction, adequate inflow and outflow are crucial for long-term patency. The impaired venous drainage causes a poor stent inflow, which has been shown to be an important risk factor for stent occlusion.²⁴ In the domain of venous angioplasty, a stent stenosis more than 50% is commonly accepted as a critical stenosis and should be considered for a re-intervention.^{11,25–27} In this study, the cumulative stent restenosis were 36.52% at 24 months and the stent occlusion appears to be related to the slowly narrowing of the stent lumen over the time other than other factors (OR: 0.910; 95% CI: 0.832–0.997; *p*-value: 0.042) (Figure 5). It expresses the necessity of thorough follow-ups, accompanying with measuring the diameter of stent lumen using DUS in a timely manner. As the result, preventive re-intervention should be considered in patients with clinical symptoms and persisting reduction of stent lumen even before reaching the critic stenosis.

Our findings identified two other factors associated with the patency of the stent: length of stented tract and duration of the operation. Longer stented area is an indicator of considerably more involvement of venous tract. Moreover, in most cases with venous pathology extending below the femoral confluence, an additional

endophlebectomy and insertion of AVF were necessary. Consequently, the recanalization in these cases is more complicated and takes more time (Figure 6).

The reported primary, assisted primary, and secondary patency after venous stenting in literature vary from 8% to 90.4%, 55% to 99%, and 30% to 100%, respectively. In general, the better patency rates were reported in studies with shorter follow-up periods, patients with acute DVT or those with more cases of May-Thurner syndrome (MTS) in patient's population. Overall, our findings are consistent with other studies of venous recanalization.^{11,14,27–32} The cumulative primary patency, assisted primary patency, and secondary patency in our study were 60.3%, 76.2%, and 87.3%, respectively. Restricting the patency rate to subcategories shows that primary patency in patients with involvement of femoral confluence are significantly lower than two other groups. However, assisted primary and secondary patency in all groups were significantly better than primary patency and statistically identical among three groups (Figure 4).

Although we believe that DUS is a good method to evaluate stent geometry and patency, it has some limitations depending on the experience of the sonographer, body habitus, and artifacts hindering the accuracy of measurements. Despite the fact that comparing the stent lumen in the exact same position was not possible during the follow-ups, our findings suggests a significant progress of stenosis in individual cases. It was also unclear from our data how sufficient was the postoperative anticoagulation and thus no conclusion regarding its effects on in-stent thrombosis can be drawn from the present data.

Figure 5. Reduction of stent area over the time and rate of primary patency.

Figure 6. Duration of the operation (a) and length of the stented area (b) in endovenous recanalization. All differences were statistically significant. The box plots represent median (bar), interquartile range (box), and absolute range (whiskers).

Conclusion

DUS shows a sufficient diagnostic accuracy in the detection of stent changes and its patency. Findings of DUS are suggestive for existing discrepancy between diameters of the stent lumen in vitro and after deployment in all patients. However, stent occlusion appears to be related to reduction of stent lumen over the time rather than the pure percent of the stenosis.

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Ethical approval

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Mohammad Esmaeil Barbati

Erklärung § 5 Abs. 1 zur Datenaufbewahrung

Hiermit erkläre ich, dass die dieser Dissertation zu Grunde liegenden Originaldaten

- bei mir, Mohammad Esmaeil Barbati, Laurentiusstrasse 60, 52072 Aachen, hinterlegt sind.

Erklärung gemäß § 5 Abs. (1) und (2), und § 11 Abs. (3) 12. der Promotionsordnung¹

Hiermit erkläre ich, **Mohammad Esmaeil Barbati**, an Eides statt, dass ich den wesentlichen Anteil an der Publikation:

Barbati M.E., Gombert A., Toonder I., van Vuuren T.M.A.J., Schleimer K., Grommes J., Wittens C.H.A., Jalaie H.: Detecting stent geometry changes after venous recanalization using duplex ultrasound; Phlebology.; 2018

Die Anteile an der Arbeit waren wie folgt:

	Barbati M.E.	Gombert A.	Toonder I.	van Vuuren T.M.A.J.	Schleimer K.	Grommes J.	Wittens C.H.A.	Jalaie H.	Summe (%)
Studienüberwachung	50	0	0	0	0	10	10	30	100
Studiendesign/Konzeption	30	10	10	0	0	10	20	20	100
Datenerhebung	60	0	10	30	0	0	0	0	100
Datenauswertung	50	10	0	0	0	10	10	20	100
Statistische Auswert.	70	10	.	0	0	10	10	0	100
Interpretation der Datenauswertung	50	0	10	0	10	0	10	20	100
Verfassung des Manuskripts	100								100
Korrektur des Manuskripts	20	10	20	0	10	10	10	20	100

Aus diesem wesentlichen Anteil ergibt sich selbstverständlich die Stellung als Erstautor.

Mohammad Esmaeil Barbati

Als Doktorvater bestätige ich die Angaben von Mohammad Esmaeil Barbati und in Vertretung für die Kooperationspartnern Irwin Toonder, Timme M.A.J. van Vuuren, Prof. Dr. med. Cees Wittens.

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Ich schließe mich der Erklärung von Univ.-Prof. Dr. med. Michael Jacobs als Koautor an

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SCIENTIFIC PUBLICATIONS

1. **Barbat ME***, Alshabat AO*, Alzoubi O, Jalaie H, Wittens CH. *Role of May-Thurner Syndrome in Recurrent thrombosis after catheter-directed thrombolysis of deep vein thrombosis. Annals of vascular surgery. 2018.*
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